REMARKS

Applicants have studied the Office Action mailed October 31, 2005 and have made amendments to the specification. It is respectfully submitted that the application, as amended, is in condition for allowance. Reconsideration and allowance of the pending claims in view of the above amendments and following remarks is respectfully requested.

Sequence Disclosures:

The Examiner stated that this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. The Examiner notes that the Sequence Listing is missing mandatory numeric identifiers <150> and <151>, prior applications and filing dates.

Applicants hereby submit a Substitute Sequence Listing that includes numeric identifiers <150> and <151> (prior applications and filing dates). The Substitute Sequence Listing adds no new matter.

Abstract:

The Examiner objected to the abstract because it does not adequately describe the claimed invention.

The abstract is hereby amended, as indicated above, to more adequately describe the claimed invention.

Title:

The Examiner objected to the title as not being descriptive and stated that a new title is required that is clearly indicative of the invention to which the claims are directed.

The title is hereby amended, as indicated above, to be more clearly indicative of the invention to which the claims are directed.

Rejection of claims 3 and 24-36 under 35 USC §112, 1st paragraph:

The Examiner rejected claims 3 and 24-36 under 35 USC §112, 1st paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had

possession of the claimed invention at the time the application was filed, and this is a new matter rejection. The Examiner states that the specification and claims as originally filed do not provide support for the invention as now claimed, specifically, A) An isolated antibody that selectively binds to a "polypeptide" (claims 3, 24, 35-36, and dependent claims 25-34) and, B) "A composition comprising the antibody...and a pharmaceutically acceptable carrier" (claims 31-34).

With respect to the term "polypeptide", Applicants respectfully assert that the terms "polypeptide" and "peptide" are used synonymously, as is conventional in the art. Thus, claims 3, 24, and 35-36 could alternatively recite "peptide" in place of "polypeptide" without altering the meaning or scope of the claims. The term "polypeptide" is used throughout these claims merely for consistency.

With respect to the phrase "A composition comprising the antibody...and a pharmaceutically acceptable carrier" in claims 31-34, claim 17 as originally filed recites "A pharmaceutical composition comprising an agent identified by the method of claim 16 and a pharmaceutically acceptable carrier therefor". The "agent" recited in this claim can be an antibody.

Rejection of claims 3 and 24 under 35 USC §102(b):

The Examiner rejected claims 3 and 24 under 35 USC §102(b) as being anticipated by Tighilet et al. as evidenced by Karls et al.

In making this rejection, the Examiner states that Tighilet teaches an antibody specific for residues 521-540 of mouse calcium/calmodulin-dependent protein kinase II β subunit (CaMKII-β) and, as evidenced by Fig. 1 of Karls, residues 521-540 of mouse CaMKII-β correspond exactly to residues 495-514 of SEQ ID NO:2 of the instant application. The Examiner states that therefore said antibody would inherently bind to a polypeptide consisting of or comprising SEQ ID NO:2.

In response, Applicants respectfully assert that Tighilet et al. (as evidenced by Karls et al.) does not anticipate claims 3 and 24.

The Examiner asserts, in effect, that the antibody taught by Tighilet et al. will inherently cross-react and thus bind to the same polypeptides (i.e., polypeptides comprising or consisting of SEQ ID NO:2) as the instantly claimed antibodies, thereby anticipating the instant claims. However, inherency may only be relied upon where the consequences of following the reference

disclosure always necessarily results in the claimed invention. If there is not a reasonable certainty that the claimed subject matter will necessarily result, the rejection is not proper.

Specifically, in order for the antibody of Tighilet et al. to inherently anticipate the instant claims, the antibody of Tighilet et al. must necessarily selectively bind to the polypeptides recited in the instant claims (i.e., polypeptides comprising or consisting of SEQ ID NO:2). It is not sufficient that the antibody of Tighilet et al. may possibly or probably bind to the polypeptides recited in the instant claims.

However, this "possibly or probably" standard appears to be the standard that the Examiner is relying on for the rejection of claims 3 and 24 under 35 USC §102(b). The Examiner has cited a reference that teaches an antibody that may possibly or probably selectively bind to polypeptides of SEQ ID NO:2 because the reference antibodies bind to a protein that has an amino acid sequence that matches a short fragment of SEQ ID NO:2 (corresponding only to residues 495-514 of SEQ ID NO:2), without providing any evidence that the reference antibodies must necessarily selectively bind to polypeptides of SEQ ID NO:2.

It is Applicant's position that the antibody of Tighilet et al. does not necessarily selectively bind to polypeptides of SEQ ID NO:2 because different epitopes must necessarily exist in the polypeptide of SEQ ID NO:2 compared with the protein of Tighilet et al. because of the extensive differences that exist in their amino acid sequences. The amino acid sequence of instant SEQ ID NO:2 differs from the protein of Tighilet et al. at least over amino acid residues 1-494 and 515-516 of SEQ ID NO:2, which is the majority of SEQ ID NO:2. Therefore, due to these substantial differences in the protein structures, the antibody taught by Tighilet et al. clearly does not necessarily cross-react with the same proteins (i.e., proteins comprising or consisting of SEQ ID NO:2) as the antibodies of claims 3 and 24.

Accordingly, Applicants respectfully request that the rejection of claims 3 and 24 under 35 USC §102(b) be reconsidered and withdrawn.

Rejection of claims 25-36 under 35 USC §103(a):

The Examiner rejected claims 25-36 under 35 USC §103(a) as being unpatentable over Tighilet et al. in view of Gavilondo et al.

In making these rejections, the Examiner states that Gavilondo et al. teaches the usefulness of monoclonal antibodies and antibody fragments for therapeutic and diagnostic purposes (i.e., as

compositions in a pharmaceutically acceptable carrier) and that antibodies can be fused with enzymes (i.e., detectably labeled). The Examiner asserts that, therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a monoclonal antibody, a composition thereof, an antibody fragment, or detectably labeled antibody as taught by Gavilondo to CaMKII-β protein as taught by Tighilet.

In light of the discussion above in regards to the anticipation rejection under 35 USC §102(b) in view of Tighilet et al., it is clear that Tighilet et al., even in combination with Gavilondo et al., neither anticipates nor makes obvious claims 25-36 due at least to the significantly different epitopes that exist because of the extensive amino acid sequence differences in the CaMKII-β protein of Tighilet et al. compared with the polypeptide of SEQ ID NO:2 of the instant application (SEQ ID NO:2 differs from the CaMKII-β protein of Tighilet et al. at least over amino acid residues 1-494 and 515-516 of SEQ ID NO:2, which is the majority of SEQ ID NO:2). This obviates the teachings of Gavilondo et al. with respect to Tighilet et al. as it applies to claims 25-36 under 35 USC §103(a).

Accordingly, Applicants respectfully request that these rejections under 35 USC §103(a) be reconsidered and withdrawn.

Conclusions

Claims 3 and 24-36 remain pending and under consideration. Claims 1-2 and 37-38 were withdrawn from consideration by the Examiner as being directed to non-elected subject matter.

In view of the above amendments and remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the objections and rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,
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